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Manual: 13A—Quality and Requirements

Management Program Documents

1. PURPOSE

This Program Requirements Document (PRD) identifies requirements and responsibilities for controlling written management direction in the form of instructions, *procedures* (see def.), and drawings that include or reference appropriate quantitative or qualitative *acceptance criteria* (see def.) for determining that the prescribed results have been satisfactorily attained. See Appendix A for requirements basis.

2. APPLICABILITY

This PRD applies to company organizations responsible for the development, review, *approval* (see def.), maintenance, use, and cancellation of new and revised instructions, procedures, and drawings for *activities affecting quality* (see def.).

3. RESPONSIBILITIES

3.1 Managers and Supervisors

Managers and supervisors are responsible for:

- A. Ensuring that activities within their area of responsibility that affect quality are prescribed by and performed in accordance with documented approved instructions, procedures, and drawings
- B. Ensuring that personnel are trained in the use of instructions, procedures, and drawings to achieve and maintain proficiency in their assigned tasks.

3.2 Cognizant Quality Engineer

The Cognizant Quality Engineer (CQE; see def.) is responsible for:

- A. Reviewing administrative and technical procedures which implement requirements of the Quality Assurance Program Requirements Documents.
- B. Reviewing procedures which incorporate independent *inspection* (see def.).
- C. Reviewing procedures that incorporate preauthorized *rework* (see def.) on nonconforming *items* (see def.).

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3.3 Company Personnel

Company personnel are responsible for:

- A. Following prescribed instructions, procedures, and drawings in the *performance* (see def.) of their assigned tasks for activities that affect quality.
- B. Reporting errors or deficiencies in instructions, procedures, and drawings to their immediate management.
- C. Identifying conditions or activities for which instructions, procedures, and drawings are needed.

4. REQUIREMENTS

4.1 Companywide Applications

The requirements identified in this subsection (4.1) apply to the entire company unless exempted by INT-17, QA PRD Introduction, Subsection 2.

4.1.1 **Basic**

- 4.1.1.1 Activities affecting quality shall be prescribed by and performed in accordance with documented instructions, procedures, or drawings that include appropriate quantitative or qualitative acceptance criteria for determining that prescribed results have been satisfactorily attained. [NQA-1-1997, Requirement 5, 100 1s; DOE/RW-0333P 5.2]
- 4.1.1.2 Activities affecting quality shall be described to a level of detail commensurate with the complexity of the activity and the need to assure consistent and acceptable results. [NQA-1-1997, Requirement 5, 100 2s]
- 4.1.1.3 The need for and the level of detail in written procedures or instructions shall be determined based on the complexity of the task, the significance or the item or activity, work environment, and worker proficiency and capability [education, *training* (see def.), experience]. [NQA-1-1997, Requirement 5, 100 3s]

4.1.2 Types of Implementing Documents

4.1.2.1 Implementing documents include documents such as procedures, instructions, and drawings, with the exception of drawings governed by PRD-5074, 3.1 Design Control. [DOE/RW-0333P 5.2.1.2s]

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4.1.2.2 The type of document to be used to perform work shall be appropriate to the nature and circumstances of the work being performed. [DOE/RW-0333P 5.2.1.1s]

4.1.3 Contents of Implementing Documents

- 4.1.3.1 Implementing documents shall include the following information as appropriate to the work to be performed [DOE/RW-0333P 5.2.2]:
 - A. Responsibilities and organizational interfaces of the organizations affected by the document. [DOE/RW-0333P 5.2.2.4]
 - B. Technical and regulatory requirements. [DOE/RW-0333P 5.2.2.B]
 - C. A sequential description of the work to be performed including controls for altering the sequence of required inspections, *tests* (see def.) and other operations. The organization responsible for preparing the document shall determine the appropriate level of detail. [DOE/RW-0333P 5.2.2.C.1s and 5.2.2.C.2s]
 - D. Quantitative or qualitative acceptance criteria sufficient for determining that activities were satisfactorily accomplished. [DOE/RW-0333P 5.2.2.D]
 - E. Prerequisites, limits, precautions, *process* (see def.) parameters, and environmental conditions. *[DOE/RW-0333P 5.2.2.E]*
 - F. Quality *verification* (see def.) points and hold points. [DOE/RW-0333P 5.2.2.F]
 - G. Methods for demonstrating that the work was performed as required (such as provisions for recording inspections and test results, check off lists, or signoff blocks).

 [DOE/RW-0333P 5.2.2.G]
 - H. Identification of the lifetime and nonpermanent QA records generated by the implementing document. [DOE/RW-0333P 5.2.2.H]
 - I. Identification of associated items and activities. [DOE/RW-0333P 5.2.2.1]

4.1.4 Review and Approval of Implementing Documents

4.1.4.1 Implementing documents shall be reviewed, approved, and controlled in accordance with PRD-5077, 6.1 Document Control. [DOE/RW-0333P 5.2.3]

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4.1.5 Compliance with Implementing Documents

4.1.5.1 Individuals shall comply with the implementing documents. However, when work cannot be accomplished as described in the implementing document, or accomplishment of such work would result in an unsafe condition or undesirable situation, the work shall be stopped as soon as it is safe to do so. Work shall not be resumed until the implementing document is changed in accordance with the appropriate procedures to reflect safe and correct work practices. [DOE/RW-0333P 5.2.4, 5.2.4.A, and 5.2.4.B; Company Imposed Requirement]

4.1.6 Records

4.1.6.1 All records designated in implementing documents as *quality* assurance records (see def.) shall be controlled in accordance with PRD-5088, 17.1 Quality Assurance Records. [Summary of records requirements from NQA-1-1997, DOE/RW-0333P, and Company Imposed Requirements]

5. **DEFINITIONS**

Refer to LST-199, Definitions, in the QA PRD Manual for the definitions of the following terms:

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acceptance criteria
activities affecting quality
approval
cognizant quality engineer
inspection
item
performance
procedure
process
quality assurance record
rework
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test

training

verification

6. REFERENCES

ASME NQA-1, Quality Assurance Requirements for Nuclear Facility Applications

DOE/RW-0333P, Office of Civilian Radioactive Waste Management, Quality Assurance Requirements and Description, Revision 10

7. APPENDICES

Appendix A, 5.1 Basis

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APPENDIX A

5.1 Basis

Source	Citation	Requirement	Comments
ASME NQA-1-1997, Quality Assurance Requirements for Nuclear Facility Applications, Requirement 5	100 1s;	4.1.1.1	Consensus Requirement (CR)
NQA-1-1997, Requirement 5	100 2s	4.1.1.2	CR
NQA-1-1997, Requirement 5	100 3s	4.1.1.3	CR
Company Imposed Requirement	N/A		Company Imposed Requirement (CIR)
DOE/RW-0333P, Office of Civilian Radioactive Waste Management Program, Quality Assurance Requirements and Description, Revision 10	5.2	4.1.1.1	CR
DOE/RW-0333P	5.2.1.1s	4.1.2.2	CR
DOE/RW-0333P	5.2.2	4.1.3.1	CR
DOE/RW-0333P	5.2.2.A	4.1.3.1.A	CR
DOE/RW-0333P	5.2.2.B	4.1.3.1.B	CR
DOE/RW-0333P	5.2.2.D	4.1.3.1.D	CR
DOE/RW-0333P	5.2.2.E	4.1.3.1.E	CR
DOE/RW-0333P	5.2.2.F	4.1.3.1.F	CR
DOE/RW-0333P	5.2.2.G	4.1.3.1.G	CR
DOE/RW-0333P	5.2.2.H	4.1.3.1.H	CR
DOE/RW-0333P	5.2.2.I	4.1.3.1.I	CR
DOE/RW-0333P	5.2.1.2s	4.1.2.1	CR
DOE/RW-0333P	5.2.3	4.1.4.1	CR
DOE/RW-0333P	5.2.2.C.1s and 5.2.2.C.2s	4.1.3.1.C	CR
DOE/RW-0333P	5.2.4, 5.2.4.A and 5.2.4.B	4.1.5.1	CR
PRD-5088, 17.1 Quality Assurance Records	All	4.1.6.1	Summary of records requirements from NQA-1-1997, DOE/RW-0333P, and Company Imposed Requirements